K122563

5. 510(k) SUMMARY

DATE: September 13, 2012

SEP 19 2012

1. Submitter:

Hologic, Inc.
250 Campus Dr.
Marlborough, MA 01752
Telephone: 508.263.8857

Contact: Sarah Fairfield, Sr. Regulatory Affairs Specialist

2. Device:

Trade Name: MyoSure XL Rod Lens Hysteroscope
Common Name: Hysteroscope and accessories
Classification Name: Hysteroscope and accessories
Class: II
Regulation number: 884.1690
Product code: HIH

3. Predicate Device:

MyoSure Rod Lens Hysteroscope (K091465)

4. Device Description:

The Myosure XL Rod Lens Hysteroscope is comprised of an oval 6.0 mm x 6.4mm OD x 184 mm long stainless steel tube containing a series of rod lenses and a 4.0 mm working channel. At the distal end of the tube, an "objective" lens captures the image of the "object". The series of "rod" lenses relays the image along the length of the tube. The image is directed by a 45° prism to an offset eyepiece that also contains "rod" lenses which relay the image along the length of the eyepiece tube. At the proximal end of the eyepiece, an "ocular" lens forms the image for the human eye and/or camera. The hysteroscope features a 0° angle of view and an 80° field of view.

The Myosure XL Rod Lens Hysteroscope also incorporates an inflow channel with stopcock, glass fibers for illumination, a 4 mm working channel and a proximal seal.

Additionally, the Myosure XL Rod Lens Hysteroscope utilizes a removable 4.0 mm OD x 283 mm length outflow channel which may be inserted through the hysteroscope's working channel. The outflow channel includes a seal to prevent distension fluid leakage from its proximal end. The seal also provides an insertion pathway for handheld instruments or cautery probes.

The Myosure XL Rod Lens Hysteroscope is intended to be sterilized prior to use.

5. Intended Use:

The Myosure XL Rod Lens Hysteroscope is used to provide viewing of the cervical canal and the uterine cavity for the purpose of performing diagnostic and surgical procedures.

6. Comparison of Technological Characteristics:

The design, principles of operation, primary functional specifications and materials of composition of the Myosure XL Rod Lens Hysteroscope are equivalent to those of the predicate Myosure Rod Lens Hysteroscope with the exception:

- the outer diameter of the working channel has been increased to 4.0mm
- the outer diameter of the hysteroscope has been increased to 6.49 x 7.64 mm (oval).

The Myosure XL Rod Lens Hysteroscope's intended use is identical to that of the predicate Myosure Rod Lens Hysteroscope (K091465).

7. Performance Testing:

The Myosure XL Rod Lens Hysteroscope complies with the functional and performance characteristics of the predicate device including flow rate testing, and seal effectiveness associated with the use of the device.

8. Conclusion:

Based on the intended use, descriptive information and performance evaluation provided in this submission, the Myosure XL Rod Lens Hysteroscope has been shown to be equivalent in technology, method of operation, functional performance and intended use to the previously referenced predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Sarah Fairfield
Senior Regulatory Affairs Specialist
Hologic, Inc.
250 Campus Drive
MARLBOROUGH MA 01752

SEP 19 2012

Re: K122563
Trade/Device Name: Myosure XL Rod Lens Hysteroscope
Regulation Number: 21 CFR§ 884.1690
Regulation Name: Hysteroscope and accessories
Regulatory Class: II
Product Code: HIH
Dated: August 22, 2012
Received: August 22, 2012

Dear Ms. Fairfield:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

4. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K122563

Device Name: Myosure XL Rod Lens Hysteroscope

Indications For Use:

The Myosure XL Rod Lens Hysteroscope is used to provide viewing of the cervical canal and the uterine cavity for the purpose of performing diagnostic and surgical procedures.

Prescription Use _X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K122563